

CHAPTER 75-03-35
PROVISION OF MEDICAL FOOD AND LOW-PROTEIN MODIFIED FOOD
PRODUCTS TO INDIVIDUALS WITH PHENYLKETONURIA AND MAPLE
SYRUP URINE DISEASE

Section

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75-03-35-01. Definitions. For purposes of this chapter:

1. "At cost" means the actual cost of the medical food plus vendor shipping and handling charges and postage costs incurred by the department.
2. "Department" means the North Dakota department of human services.
3. "Government program" includes North Dakota medicaid, healthy steps, children's health insurance plan, and women, infants, and children nutrition program.
4. "Low-protein modified food product" means a food product that is specially formulated to have less than one gram of protein per serving and is intended to be used under the direction of a physician for the dietary treatment of a metabolic disease. The term does not include a food that is naturally low in protein.
5. "Maple syrup urine disease" means an inborn error of metabolism, referred to as MSUD.
6. "Medicaid" means a program implemented pursuant to North Dakota Century Code chapter 50-24.1 and 42 U.S.C. 1396 et seq. to furnish medical assistance, as defined in 42 U.S.C. 1396(d)(a), to persons determined to be eligible.
7. "Medical food" means a food that is intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and is formulated to be consumed or administered under the direction of a physician.
8. "Medically necessary" means use of low-protein modified food products for the treatment of phenylketonuria or maple syrup urine disease, which is recommended based on standards of accepted medical practice.
9. "Phenylketonuria" means an inborn error of metabolism, referred to as PKU.

10. "Qualified health care provider" means a physician who is licensed to practice medicine, a multidisciplinary metabolic clinic team, or a licensed, registered dietitian.
11. "Resident" means an individual with phenylketonuria or maple syrup urine disease who lives within the state of North Dakota with the intent to make it a fixed and permanent abode and manifests the genuineness of that intent by establishing an ongoing physical presence within the state with indicia that such presence is something other than merely transitory in nature.
12. "Treatment services" means provision of medical food and low-protein modified food products.

History: Effective November 1, 2002.

General Authority: NDCC 25-17-02

Law Implemented: NDCC 25-17-00.1, 25-17-03

75-03-35-02. Provision of medical food at no cost.

1. The department shall provide medical food at no cost to males under age twenty-two and females under age forty-five who are diagnosed with phenylketonuria or maple syrup urine disease, regardless of income.
2. The department shall provide medical food only to an individual who is a resident of North Dakota.
3. If an individual meets the requirements of this chapter, the department shall provide to the individual an initial supply of medical food. Within thirty days of the initial request to the department for medical food, an individual or the parent or legal guardian of a minor must submit the following information to the department before additional medical food will be provided:
 - a. The diagnosis of a qualifying condition; the name, address, and telephone number of the individual's physician, metabolic clinic team, or dietitian who has recommended use of the medical food; and written consent of the individual requesting medical food authorizing the physician, metabolic clinic team, or dietitian who has recommended use of the medical food to verify to the department in writing the diagnosis and recommended treatment; or

- b. Documentation from a physician that confirms the diagnosis of phenylketonuria or maple syrup urine disease and specifies recommended treatment.

History: Effective November 1, 2002.

General Authority: NDCC 25-17-02

Law Implemented: NDCC 25-17-03

75-03-35-03. Sale of medical food at cost.

1. The department shall offer for sale at cost medical food to males age twenty-two and over and females age forty-five and over who are diagnosed with phenylketonuria or maple syrup urine disease, regardless of income. The individual requesting medical food at cost must make payment to the department prior to delivery.
2. The department shall sell medical food at cost only to an individual who is a resident of North Dakota.
3. If an individual meets the requirements of this chapter, the department shall sell at cost to the individual an initial supply of medical food. Within thirty days of an initial request, an individual requesting medical food at cost must submit to the department the following before additional orders will be filled:
 - a. The diagnosis of a qualifying condition; the name, address, and telephone number of the physician, metabolic clinic team, or dietitian who has recommended use of the medical food; and written consent authorizing the physician, metabolic clinic team, or dietitian who has recommended use of the medical food to verify to the department in writing the diagnosis and recommended treatment; or
 - b. Documentation from a physician that confirms the diagnosis of phenylketonuria or maple syrup urine disease and specifies recommended treatment.

History: Effective November 1, 2002.

General Authority: NDCC 25-17-02

Law Implemented: NDCC 25-17-03

75-03-35-04. Provision of low-protein modified food products.

1. The department shall provide low-protein modified food products, if medically necessary as determined by a qualified health care provider, to males under age twenty-two and females under age forty-five who are eligible to receive medicaid benefits and are diagnosed with phenylketonuria or maple syrup urine disease.

2. An individual requesting low-protein modified food products must be eligible for medicaid benefits at the time of the request and must be a resident of North Dakota.
3. If an individual meets the requirements of this chapter, the department shall provide to the individual an initial supply of low-protein modified food products. Within thirty days of the initial request for low-protein modified food products, an individual or the parents or legal guardian of a minor must submit the following information to the department before additional orders will be filled:
 - a. The diagnosis of a qualifying condition; the name, address, and telephone number of the physician, metabolic clinic team, or dietitian who has recommended use of the low-protein modified food products, and written consent authorizing the physician, metabolic clinic team, or dietitian who has recommended use of the low-protein modified food products to verify to the department in writing the diagnosis and recommended treatment; or
 - b. Documentation from a physician that confirms the diagnosis of phenylketonuria or maple syrup urine disease and specifies recommended treatment.
4. The department may seek reimbursement from government programs for the cost of medical food and low-protein modified food products that are provided for individuals covered by those programs. The department shall encourage an individual who qualifies for the women, infants, and children nutrition program to enroll for access to medical food through that program.

History: Effective November 1, 2002.

General Authority: NDCC 25-17-02

Law Implemented: NDCC 25-17-03

75-03-35-05. Collaboration with state department of health. The department shall collaborate with the state department of health to implement the medical food program described in this chapter. The department may request information from and provide information to the state department of health regarding individuals with positive screening results for metabolic diseases. The department shall treat such information as confidential as required by law.

History: Effective November 1, 2002.

General Authority: NDCC 25-17-02

Law Implemented: NDCC 25-17-03